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"A Study Protocol on the Efficacy of Lavangadya Choorna in the Management of Tundikeri, Tonsillitis in Children –A Randomised Control Trial"

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I. BACKGROUND AND RATIONALE

Tundikeri (Tonsillitis) is one among the Mukha Rogas (diseases of oral cavity)which is caused by vitiation of Kapha and Rakta .[1]Acharya Sushruta has explained Tundikeri as Talugataroga[2] (diseases of palate) while Acharya Vagbhata has explained this as a Kantagataroga[3] (diseases of throat).The swelling in Tundikeri resembles to Vanakarpasa Phala[2] (cotton fruit) occurs at the Hanusandhi Ashrita Kantha Pradesha (submandibular region).[3] On the basis of sign and symptoms[2] of Tundikeri such as Shopha (inflammation), Toda (pain), Daha (sore throat), Prapaka (suppurative inflammation) it can be co-related to disease tonsillitis in contemporary science.

Inflammation of palatine tonsils is called tonsillitis, characterized by sore throat, dysphagia, halitosis, earache, malaise, loss of appetite, cough and fever.[4] It is a common condition with nearly all children being infected at least once[5] and greatest prevalence occurs in 5-15years old .[6] Tonsillitis accounts for about 7% of all visits to the pediatrician.[7]

Medical management with anti-inflammatory, NSAID'S, antibiotics, analgesics can give temporary relief but cannot check the recurrence of the disease. Repeated administration of antibiotics may lead to GI tract disturbance and suppression of immunity. If the tonsillitis is associated with recurrent attacks of throat infection, hypertrophy causing upper airway obstruction, peritonsillar abscess, suspicion of malignancy, the patient might have to undergo a tonsillectomy. Surgical removal affects immune system. So, there is a need of effective, non-surgical intervention in management of tonsilitis.[8]Ayurvedic treatment has a specific utility in the management of Tundikeri. Till date in Ayurveda only few scientific studies have been conducted on palliative management of Tundikeri in children, where effectiveness of Kumarabharana rasa,[9]Tankanamadhu Pratisarana (anointing), Kanchanara Guggulu,[10] is studied against Tundikeri and all the studies have shown significant results. Trisamachoorna mentioned in Shotha Chikitsa (treatment for swelling) of Kashyapa Samhitha has proven effective in the management of Tundikeri.[11]Trisamachoorna contains Hareetaki (Terminalia chebula Retz.),Shunti(Zingiber officinale Rose.) and Guduchi(Tinospora cordifolia(Willd.)Miers.) given with honey as Anupana (adjuvant)proved effective in relieving signs and symptoms of Tundikeri and showed immunomodulatory effects in children.[12]

Lavangadyachoorna mentioned in Sharangadhara Samhita indicated in Kantagata Roga[13] contains 18 herbs is said to possess properties like Vanhi Deepana(kindles Agni), Tridoshahara(alleviates Tridoshas),Rujahara (relieves pain) and Balavardhana (improves strength) . Lavanga (Syzygium aromaticum Linn.)contain 15 to 20 % volatile oil in which 85-92% eugenol is present.[14]Ela (Elettaria cardamomum (Linn.) R.Br) contain α-terpinyl acetate,[15] Twak (Cinnamomum zeylanicum Blume) contain (E)-cinnamaldehyde, these are natural anesthetic and antibacterial, and it work well at reducing inflammation. Euginol has bactericidal

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effect against both gram positive and negative bacteria.[16]Considering the therapeutic effect of the ingredients present in the Lavangadya Choorna is expected to be very effective, safe and non-surgical intervention in management of tonsillitis. So, the present study intends to evaluate the effect of Lavangadya Choorna in the management of tonsillitis in children.

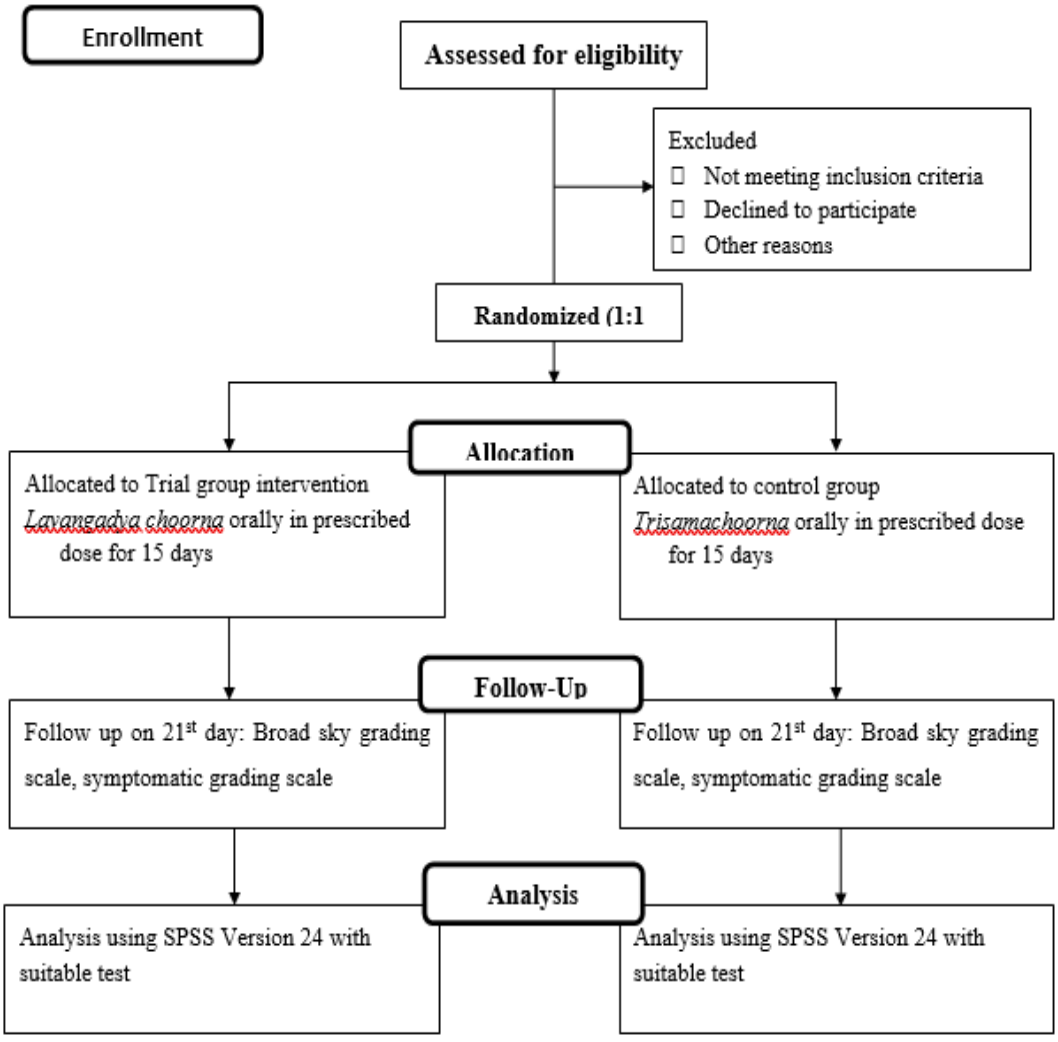
Objectives

- Primary objective is to evaluate the efficacy of Lavangadya Choorna on tonsillar enlargement based on Broadsky grading scale.[17]
- Secondary objective is to assess the improvement in the quality of life by reducing the signs and symptoms of Tundikeri,Tonsillitis using symptomatic grading.

Study design and clinical source

The study is a single center, double arm, open labelled, randomized prospective interventional trial designed to evaluate the efficacy of Lavangadya Choorna in managing Tundikeri in children. The clinical participants for trial and control group will comprise children aged 5-15 years, of either gender, presenting with enlarged tonsils and at least two or more symptoms. They will be recruited from the Outpatient department and Inpatient department of Kaumarabhritya at Shri Dharmasthala Manjunatheswara Institute of Ayurveda and Hospital, Bengaluru.

Figure No 1: Showing Consort flow diagram of the study



ELIGIBILITY CRITERIA ICD-10 CODE: J03.9

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Participants

The study will recruit children aged between 5-15 years, of either gender, presenting with enlarged tonsils accompanied by two or more symptoms as outlined in the diagnostic criteria. Children under 5 years and over 15 years of age, Grade IV tonsils presenting with complications such as peritonsillar abscess, parapharyngeal abscess, tonsillar cyst, tonsillolith will not be eligible. Those with other acute or chronic system illnesses or those undergoing other interventions, will also be excluded. Furthermore, children presenting with pharyngitis will not be included in the study. Upon obtaining informed consent from parents, eligible chilren will be randomly allocated to two distinct groups in 1:1 allocation ratio.

Diagnostic criteria:

The subjects will be diagnosed based on clinical signs and symptoms of Tundikeri,Tonsillitis.

- Gala Shopha (Enlargement of tonsils)
- Gala Prapaka (Hyperemia)
- Gala Daha (Sore throat)
- Gala Shotha(Dysphagia)
- Jwara (Fever)
- Gala Toda (Pain the throat)
- Halitosis
- Jugulodigastric Lymph Node Enlargement
- Cough (productive/non productive)

INTERVENTIONS

Drug source: The raw materials required for preparing Lavangadya Choorna and Trisamachoorna will be sourced from certified vendors. Its identification, authentication, preparation, packing and labeling will be done from SDMIAH teaching pharmacy Bengaluru.

Trial group will receive Lavangadya choorna orally, with varying dosage as per age, thrice daily with Madhu (honey) after food for a duration of 15 days, followed by a post treatment follow up on 21st day.

Table no1: Showing Posology of trial drug

Drug	Lavangadya Choorna
Dosage	5-9 years – 2g TID after food 10-15 years-3g TID after food
Anupana	Madhu QS
Treatment duration	15 days
Follow up	On 21st day

Control group will receive Trisamachoorna, with varying dosage as per age, thrice daily with madhu after food for a duration of 15 days, followed by a post treatment follow up on 21st day.

Table no 2: Showing Posology of trial drug

Drug	Trisamachoorna
Dosage	5-9 years – 2g TID after food 10-15 years-3g TID after food
Anupana	Madhu QS
Treatment duration	15 days
Follow up	On 21st day

Withdrawal criteria

Subjects may be withdrawn from the study at any point if they experience adverse events, fail to adhere to the study protocol, develop new or worsening medical conditions and are lost to follow up, as determined by the researcher.

OUTCOMES

Primary outcome measure

Reduction in tonsillar enlargement as assessed using Broadsky grading scale.

1. Broadsky grading scale[17]

This is a standardized grading scale to access tonsil size. It categorizes tonsils into four grades based on the percentage of the occupying of oropharyngeal airway.

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Table no 3: Showing Broadsky grading scale

Grade	Description
0	Tonsils within the tonsillar fossa
1	Tonsils just outside the tonsillar fossa and occupy <25% of oropharyngeal width
2	Tonsils occupy 26-50%of oropharyngeal width
3	Tonsils occupying 51-75% of oropharyngeal width
4	Tonsils occupy >75% of oropharyngeal width

Secondary outcome measure

Clinically significant improvement in the symptoms of Tundikeri, tonsillitis as evaluated using symptomatic grading scale ranging from 0 to 3, with higher scores indicating greater symptom severity.

Table no 4: Showing Symptomatic grading

Symptom	Grade 0	Grade 1	Grade 2	Grade 3
Gala Shotha(Dysphagia)[18]	No difficulty in swallowing	Patient feels difficulty in swallowing of solid matters	Patient unable to swallow even saliva	Patient unable to open mouth completely due to severe pain
Gala Prapaka[18]	No change in colour of mucous membrane	Redness present only over peritonsillar surface	Redness present on both anterior and posterior pillars	Redness present completely over oropharynx including tonsils
Jwara[18]	Normal temperature 98.6F	Temperature rises from 98.6F -100F	Temperature rises from 100F-102 F	Temperature more than 102F
Gala Toda[18]	No pain	Mild tolerance on pressing	Pain during deglutination	Pain during rest
Gala Daha[10]	No burning sensation	Occasional localized burning sensation	Localized mild burning sensation in a particular hour of the day	Burning sensation throughout the day but tolerable
Enlargement of Jugulodigastric lymph nodes [10]	No palpable lymph nodes	Palpable lymph nodes Unilateral	Palpable lymph nodes Bilateral	Enlargement bilateral, visible and prominent
Halitosis [10]	Halitosis absent	Halitosis present only when opening of moth angle completely	Halitosis present during yawning	Halitosis present even during talking
Cough (productive/non productive)[10]	Absence of bouts of cough	Less than 3 bouts of cough/hour	3-5 bouts of cough / hour	5-7 bouts of cough / hour

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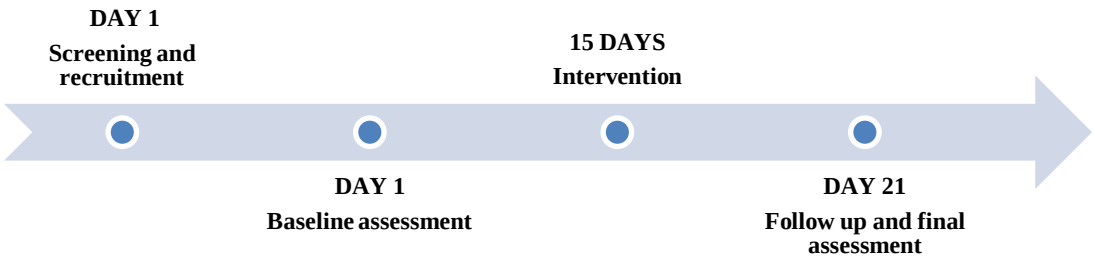
PARTICIPANT TIMELINE

Figure no 2: Showing Participant timeline



SAMPLE SIZE

The sample size was calculated based on the standard deviation and percentage improvement observed in a previous trial, ensuring adequate power to detect statistically significant differences. The sample size for the current study was derived using below formula and was determined to be 16.

$N= 2(SD)^2 X (Z(1-\alpha) +Z \beta)2 / d2$

Standard Deviation = 0.50

Z ȣ = Power of the study= 0.84

Z(1-α) = Level of confidence= 1.96

d=0.5

N= 2 X (0.50)2 X (1.96 + 0.84)2 / (0.5)2

= 2 X 0.25 X 7.84 / 0.25

= 15.68

= 16

Considering a 10% dropout rate, the adjusted sample size was calculated using the formula N=n/(1-d), which yielded an adjusted sample size of 18 for a single group. Therefore, the total sample size for the study is 36.

Table no 5: Sample size for trial and control group

Trial group	Group A- Lavangadyachoorna	18 children
Control group	Group B -Trisamachoorna	18 children

RECRUITMENT

The study will recruit children between 5-15 years of age, of either gender, presenting with signs and symptoms of Tundikeri (Tonsilitis). Participants will be selected from the outpatient department and inpatient department of Kaumarabhritya department at Shri Dharmasthala Manjunatheswara Institute of Ayurveda and Hospital, Bengaluru.Both the trial group and control group will be recruited from the same population using the same inclusion and exclusion criteria.

Assignment of interventions

Allocation:

Sequence generation: Computer generated random allocation will be used to assign participants to either the trial group or control group

Allocation concealment mechanism: Random allocation using computer generated random tickets which will be kept labeled in a sealed cover

Implementation: The sealed covers containing the random tickets will be opened in front of guide at the start of the intervention.

Blinding: This study will employ an Open label design, where both the researcher and participant will be aware of the group assignments.

II. DATA COLLECTION, MANAGEMENT, AND ANALYSIS

Data will be collected using a specially designed Case Report Form (CRF) that incorporates assessment scales. The researcher will

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enter the collected data into the CRF, which will then be transferred to MS office excel and SPSS version 20 for statistical analysis. Both descriptive and inferential statistics will be used to analyse the collected data. Descriptive Statistics will be used to summarize the demographic data and other relevant information, expressed in frequency (f), percentile (%), range and Median. Ordinal data will be expressed in mean, standard deviation and standard error. The Shapiro Wilk test will be used to assess normality, and based on the results, either parametric test or non-parametric test will be employed. For inferential statistics, the study will analyze both qualitative and quantitative data. A significance level of $p < 0.05$ will be used. Non-parametric tests, including Friedman's test and post-hoc Wilcoxon signed rank test, will be used for within-group comparisons, while the Mann-Whitney U test will be used for between-group comparisons. Parametric tests, such as paired t-tests and unpaired t-tests, will also be employed, along with repeated measures ANOVA. The magnitude of the tests will be evaluated using Cohen's D effect size. All statistical analyses will be performed using SPSS version 24.

Data monitoring

The researcher and guide will closely monitor the study data, ensuring the adherence to the intervention protocol, tracking adverse effects and overseeing participant enrolment. They will also conduct audits, perform interim analysis and report any ADR or changes in study protocol to the Ethical Review Board via principal investigator. The investigator may terminate the participant from the study if their continued participation poses a risk to their safety or wellbeing.

Specifically, withdrawal may occur if adverse effects require immediate attention or if the investigator determines that remaining in the study could cause harm to the participant.

Safety measures and managing adverse effects

Although the study protocol is expected to be safe for children, the monitoring team will closely track any unexpected occurrences during the intervention period. In the event of an adverse reaction, the relevant authority will be promptly informed. Parents/ guardians will record any issues in their log and notify the principal investigator. All significant adverse events will be documented and published in final record.

III. ETHICS AND DISSEMINATION

Research ethics approval

On October 3, 2023, the Institutional Ethics Committee of Shri Dharmasthala Manjunatheshwara Institute of Ayurveda and Hospital (SDMIAH) granted the trial ethical approval (SDMIAH/IEC/37/2023). On 19/08/2024, the trial has been registered prospectively with the Clinical Trial Registry India (CTRI) (CTRI/2024/08/072645). Confidentiality and anonymity will be maintained throughout the study. Upon completion of the trial, the anonymized data will be made accessible to the primary investigator, data auditors ensuring transparency and accountability.

Protocol amendments

Any modifications to the study protocol will be communicated to relevant authority inclusive of investigator, guide, Institutional ethics committee (IEC), participant and their family and trial registry (CTRI). All changes will be documented, justified and will be as approved by IEC prior to implementation.

Study Recruitment status

Recruitment for the study is currently open and underway. As of now, 18 subjects have successfully enrolled in the study.

Informed consent, Confidentiality and Access to data

Prior to enrolment, written informed consent/assent will be obtained from parents by designated investigator. The consent will be taken abiding the protocol and will ensure participant understanding of the study purpose, procedures, risk and benefits. Personal and medical information gathered during the study will be strictly confidential. Access to the information will be limited to authorised personnel, who may review records for specific purpose, including result analysis, ensuring study integrity by IEC members and rare court proceedings. Identity of child will remain anonymous and name will not be disclosed.

Declaration of interests: The author declares no conflict of interest

Ancillary and post-trial care

In the event of any adverse event resulted from the trial participation, the researcher will ensure appropriate treatment or referral to guarantee necessary care. After study completion, participants were advised to follow dietary

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recommendations. However, no formal post-trial care was advised.

Dissemination policy

The study data will be published in indexed scientific journal and if feasible, may be presented at seminars/ Conference.

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अमूर्त

परिचय: तुंडिकेरी मुख रोगों में से एक है जो कफ और रक्त के विष्ट होने के कारण होता है। आचार्य सुश्रुत ने टुंडीकेरी को तालुगातारोगा के रूप में समझाया है जबकि आचार्य वागभट ने इसे कांटगातारोगा के रूप में समझाया है। टुंडिकेरी के संकेत और लक्षणों के आधार पर जैसे शोफा (सूजन), टोडा (दर्द), दाहा (गले में खराश), प्रपाका (सप्यूर सूजन) यह समकालीन विज्ञान में रोग टॉन्सिलिटिस से सह-संबंधित हो सकता है। यह एक आम स्थिति है जिसमें लगभग सभी बच्चे कम से कम एक बार संक्रमित होते हैं और सबसे अधिक प्रसार 5-15 वर्ष की आयु में होता है। बाल रोग विशेषज्ञ के सभी दौरे के लगभग 7% के लिए टॉन्सिलिटिस होता है। आयुर्वेदिक उपचार की टुंडिकेरी के प्रबंधन में एक विशिष्ट उपयोगिता है। कंटागाटा रोगा में संकेतित शरंगधार संहिता में वर्णित लवंगाडिया चूरना में 18 जड़ी-बूटियां होती हैं, जिन्हें कहा जाता है कि इसमें वन्ही दीपाना, त्रिदोशा हारा, रुजाहारा और बालवर्धन जैसे गुण होते हैं। लवंगाड्या चूरना में मौजूद अवयवों के चिकित्सीय प्रभाव को ध्यान में रखते हुए टॉन्सिलिटिस के प्रबंधन में बहुत प्रभावी, सुरक्षित और ग़ैर-सर्जिकल हस्तक्षेप होने की उम्मीद है। इसलिए, वर्तमान अध्ययन का उद्देश्य बच्चों में टॉन्सिलिटिस के प्रबंधन में लवंगाड्या चूरना के प्रभाव का मूल्यांकन करना है। सामग्री और तरीक़े: वर्तमान शोध एक संभावित, ओपन-लेबल, यादृच्छिक नियंत्रित नैदानिक परीक्षण है जिसमें टुंडिकेरी के निदान वाले 36 प्रतिभागियों का कुल नमूना आकार शामिल है। परीक्षण समूह के प्रतिभागियों को 15 दिनों की अवधि के लिए भोजन के बाद मधु के साथ दिन में तीन बार, उम्र के अनुसार अलग-अलग खुराक के साथ मौखिक रूप से लवंगाड्या चूरना प्राप्त होगा। नियंत्रण समूह के प्रतिभागियों को मौखिक रूप से त्रिसमाचोरना प्राप्त होगा, उम्र के अनुसार अलग-अलग खुराक के साथ, 15 दिनों की अवधि के लिए भोजन के बाद मधु के साथ दिन में तीन बार। निष्कर्ष: अध्ययन के निष्कर्ष संभावित रूप से प्रदर्शित कर सकते हैं कि लवंगाड्या चूरना का मौखिक प्रशासन टुंडिकेरी के प्रबंधन में त्रिसमाचोर्न के रूप में प्रभावी हो सकता है।

कीवर्ड -आयुर्वेद, लवंगड्या चूरना, टॉन्सिलिटिस, टुंडिकेरी

APPENDICES
CONSENT/ ASSENT FORM

TITLE OF SYNOPSIS:
STUDY ON THE EFFICACY OF LAVANGADYA CHOORNA IN THE MANAGEMENT OF TUNDIKERI, TONSILLITIS IN CHILDREN- AN OPEN LABEL RANDOMISED CONTROLLED CLINICAL TRIAL.

1. Consent / Assent Form - To be Signed on the day of Screening
2. Participant enrollment ID for this trial: ----------
3. Name of the Investigating Physician (Research Scholar): Dr. Mamata
4. Name of the Guide: Dr.Srilakshmi
5. I confirm that I have read / the study has been explained to me adequately and I have understood the information sheet for the above study and had the opportunity to ask questions.
6. I hope to complete the study, but I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason, and without my medical care or legal rights being affected.
7. I understand that my doctor will provide information about my progress, in confidence, to the related authorities. I understand that the information held by the Investigators and researchers and records maintained by the concerned authorities might be used to follow up my health status.
8. I understand that the information will be used for medical research only and that I will not be identified in any way in the analysis and reporting of the results. I understand that sections of any of my medical notes may be looked at by the authorities or responsible individuals from the members of the IEC, Regulatory authorities or Court, if necessary. I give permission for these individuals to have access to my records.
9. I understand what is involved in this trial and agree to take part in the clinical trial for a period of 15 days.

Name of the Patient/ Parent(s) / Guardian(s)
Signature with Date

Signature
Dr.Mamata

Signature
Guide Name: Dr.Srilakshmi

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